

B. Effects of Germination Activated Ganoderma Spores on ASC (asymptomatic carriers) and CHB (chronic hepatitis B)

The therapeutic effects of ganoderma spores on ASC and CHB patients were similar and statistically insignificant.

C. Treatment Courses on Therapeutic Effects of Germination Activated Ganoderma Spores

As shown in Table 22, the therapeutic effects after two courses of treatment with ganoderma spores are better than one course of treatment with ganoderma spores. As indicated above, the 1<sup>st</sup> treatment course was continued for 45 days. After discontinued for 15 days later, the treatment was resumed (2<sup>nd</sup> treatment course) for additional 45 days.

TABLE 22

Treatment Courses on Therapeutic Effects of Ganoderma Spores				
	Case Number	Negative HBeAg	Positive HBeAb	Negative HBV DNA
1 <sup>st</sup> treatment course	7	1	1	1
2 <sup>nd</sup> treatment course	7	1	4	4

D. Observations for Adverse Effects After Treatment with Germination Activated Ganoderma Spores

All 14 patients completed the entire treatment program. Non has shown any fever or skin irritations. All patients maintained normal appetite and sleep pattern. The results of these studies indicate that the germination activated sporoderm-broken ganoderma spores were clinically safe with no apparent adverse effects on patients.

#### Clinical Example 2

#### Clinical Observations

The following are individual observations on patents treated with sporoderm-broken ganoderma spores.

1. Patient N: male, age 36.

Diagnosis: liver hepatitis B carrier; mother died of liver cancer "a few years ago".

Patient N was given high dose of sporoderm-broken ganoderma spores between March, 1999 and September, 1999. In September, patient N's fatty liver and gall bladder polyps disappeared. Also, his HBV DNA was greatly reduced.

Date	Observation	Change
March 1999	Fatty liver Gall bladder polyps	
July 1999	HBV DNA 3490 pg/ml	
September 1999	HBV DNA 620 pg/ml Normal liver	Reduced to normal range

2. Patient L: male, age 62.

Patient L was diagnosed with hepatoma (tumor size: 5.1×6.6×7.7 cm) with tumor located at the portal vein region of the liver. He started high dose of ganoderma spores treatment in May, 1999. In August, 1999, X-ray data confirmed that his tumor reduced to 3.5×3.4×3 cm. Between May and August, 1999, ganoderma spores were the only medicine that patient L had taken.

Date	Observation	Change
May 1999	Confirmed liver cancer Tumor size 5.1 × 6.6 × 7.7 cm Other satellite tumors present	
August 1999	Tumor size 3.5 × 3.4 × 3 cm	

3. Patient C: Male, age 44.

Patient C was diagnosed with hepatitis B and early liver cirrhosis, and was admitted to hospital since 1997. Patient

Date	Observation	Change
March 1999	Hepatitis B and jaundice Liver hepatitis B and only cirrhosis	Started treatment
Present	HBV DNA 5 pg/ml	

4. Patient L-1: male, age 67

Patient L-1 was diagnosed with poor glucose control for 10 years even after injection of insulin. In March, 1999, Patient L-1's hemoglobin Alc (HbAlc) was 16.4%. Patient L-1 started high dose of germination activated sporoderm-broken ganoderma spores treatment in March, 1999. In August, 1999, his HbAlc reduced to 10%, which was within the range of moderate glucose control.

Date	Observation	Change
March 1999	Hb Alc 16.4%	
August 1999	Hb Alc 10%	

Treatment started in March. Result: moderate glucose control.

While the invention has been described by way of examples and in terms of the preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments. On the contrary, it is intended to cover various modifications as would be apparent to those skilled in the art. Therefore, the scope of the appended claims should be accorded the broadest interpretation so as to encompass all such modification.

What is claimed is:

1. A method for producing sporoderm-broken ganoderma spores comprising:

soaking ganoderma spores in a solution which is selected from the group consisting of water, saline, and a nutritional solution to cause the spores to germinate; placing said germinated spores in a culture box to activate said germinated spores at relative humidity of 65–98% and temperature of 18–48° C. so as to enhance production of bioactive substances in said germination activated ganoderma spores; and

treating the germination activated ganoderma spores with an enzyme with cell wall dissolving property to produce said sporoderm-broken ganoderma spores.

2. The method for producing sporoderm-broken ganoderma spores according to claim 1, wherein said enzyme is chitinase or cellulase.

3. The method according to claim 1, wherein wherein said spores are soaked in the solution for 30 minutes to 8 hours at no more than 50° C.

4. The method for producing germination activated ganoderma spores according to claim 3, wherein said spores are soaked in the solution for 2 to 4 hours.

5. The method according to claim 3, wherein said spores are soaked in the solution at 20 to 43° C.

6. The method according to claim 1, wherein said nutritional solution is at least one selected from the group consisting of coconut juice, malt extract, ganoderma sporocarp extract, ganoderma capillitia extract, culture solution containing biotin, and culture solution containing monobasic potassium phosphate and magnesium sulfate.

7. The method according to claim 1, wherein said solution is 0.1–5 times the weight of said spores.

8. The method according to claim 1, wherein said bioactive substances are selected from the group consisting of active genes and promoters, active enzymes, sterols, cytokines, interferons, lactone A, ganoderma acid A, triterpenes, polysaccharides, vitamins, superoxide dismutases (SOD), vitamin E, glycoproteins, and growth factors.

9. A method for extracting bioactive substances from germination activated ganoderma spores comprising:

drying the sporoderm-broken ganoderma spores according to claim 1 at low temperature; and

extracting the dried sporoderm-broken ganoderma spores.

10. The method for extracting bioactive substances from germination activated ganoderma spores according to claim 9, wherein said drying is freeze-drying or vacuum-drying.

11. The method for extracting bioactive substances from germination activated ganoderma spores according to claim 9, wherein said bioactive substances are extracted by water, alcohol, or thin film condensation.

12. A method for producing sporoderm-broken ganoderma spores comprising:

soaking ganoderma spores in a solution which is selected from the group consisting of water, saline, and a nutritional solution to cause the spores to germinate;

placing said germinated spores in a culture box to activate said germinated spores at relative humidity of 65–98% and temperature of 18–48° C. to enhance production of bioactive substances in said germination activated spores; and

treating the germination activated ganoderma spores with a mechanical force to produce said sporoderm-broken ganoderma spores.

13. The method for producing sporoderm-broken ganoderma spores according to claim 12, wherein said mechanical force is at least one selected from the group consisting of micronization, roll pressing, grinding, ultrasound, and super high pressure microstream treatment.

14. The method according to claim 12, wherein said spores are soaked in the solution for 30 minutes to 8 hours at no more than 50° C.

15. The method for producing germination activated ganoderma spores according to claim 14, wherein said spores are soaked in the solution for 2 to 4 hours.

16. The method according to claim 14, wherein said spores are soaked in the solution at 20 to 43° C.

17. The method according to claim 12, wherein said nutritional solution is at least one selected from the group consisting of coconut juice, malt extract, ganoderma sporocarp extract, ganoderma capillitia extract, culture solution containing biotin, and culture solution containing monobasic potassium phosphate and magnesium sulfate.

18. The method according to claim 12, wherein said solution is 0.1–5 times the weight of said spores.

19. The method according to claim 12, wherein said bioactive substances are selected from the group consisting of active genes and promoters, active enzymes, sterols, cytokines, interferons, lactone A, ganoderma acid A, triterpenes, polysaccharides, vitamins, superoxide dismutases (SOD), vitamin E, glycoproteins, and growth factors.

20. A method for extracting bioactive substances from germination activated ganoderma spores comprising:

drying the sporoderm-broken ganoderma spores according to claim 12 at low temperature; and

extracting the dried sporoderm-broken ganoderma spores.

21. The method for extracting bioactive substances from germination activated ganoderma spores according to claim 20, wherein said drying is freeze-drying or vacuum-drying.

22. The method for extracting bioactive substances from germination activated ganoderma spores according to claim 20, wherein said bioactive substances are extracted by water, alcohol, or thin film condensation.

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